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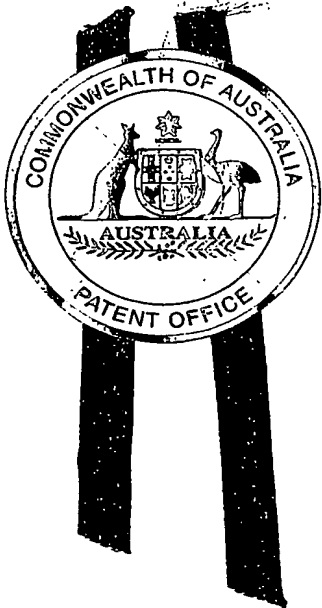
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I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2002953557 for a patent by JOHN DOMINIC PERRIER as filed on 18 December 2002.



WITNESS my hand this
Fourth day of November 2003

A handwritten signature in cursive script, reading "J. Billingsley".

**JULIE BILLINGSLEY
TEAM LEADER EXAMINATION
SUPPORT AND SALES**

AUSTRALIA

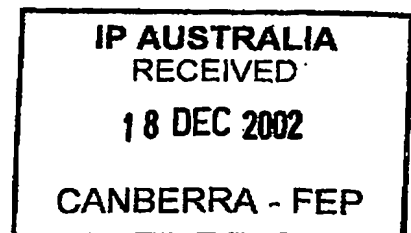
Patents Act 1990

PROVISIONAL SPECIFICATION

Invention Title:

ULTRASONIC MEDICAL DEVICE

The invention is described in the following statement:



ULTRASONIC MEDICAL DEVICE

FIELD OF THE INVENTION

5 This invention relates to medical devices in particular but not limited to an ultrasonic apparatus adapted to induce a reflexive coughing response in a patient or an animal.

BACKGROUND OF THE INVENTION

10

It is well known that the coughing reflex is a vital part of maintaining normal function as it acts to clear the lungs of excessive secretions such as mucus or other inhaled substances.

15 In some cases, human patients and animals are unable to cough on demand, rendering them liable to the exacerbation or prolongation of respiratory disease.

20 Those people who are unable to cough on demand include those who are very young, gravely ill and incapacitated patients, unconscious or heavily sedated patients, patients which have undergone a near drowning experience or overdosed on drugs which have suppressed their central nervous system, victims of stroke, elderly patients who have lost control of their body functions, intubated and incubated patients with temporary airways such as those in intensive care situations and patients who are anaesthetized during or immediately post surgery. Such conditions also exist in the veterinary context for animals.

25 Prior art methods of clearing the upper respiratory tract of mucus or to induce a coughing reflex is usually through the introduction by intubation of the upper airways tract such as with vacuum drainage or pulmonary lavage catheters. The problem with the introduction of such devices is that this is an artificial and largely inefficient method to clear the mucus or other secretions
30 blocking the lower respiratory airways. To be precise, it does not have the benefit of the explosive clearing mechanism normally associated with a coughing

spasm. Furthermore while the upper respiratory tract may be cleared by suction, smaller airways such as the bronchi and bronchioles cannot be so easily cleared.

Every year, tens of thousands of people die because of respiratory problems. Foremost among these deaths are sufferers of the following conditions:

- respiratory illnesses;
- bronchitis (acute and chronic);
- pneumonia
- chest infections (bacterial and microbial);
- paediatric respiratory problems;
- cystic fibrosis
- bronchiolitis (a paediatric form of bronchitis);
- pneumonia;
- burns victims;
- drowning victims; and
- self aspiration – for example, after a drug or alcohol overdose.

Many of these people die because their lungs fill with excessive secretions or fluids. The usual human method for self-clearing the lungs is to cough. However, huge sections of our population are unable to cough effectively, rendering them vulnerable to respiratory problems and premature death.

Even in a hospital environment, the method of clearing the chests of such patients is ineffective. Usually, a suction catheter is used to draw the secretions out of the lungs. One major problem with this method is that only the very uppermost airways are cleared. As the catheter cannot penetrate into the mid or lower airways, almost all of the secretions stay put. Pneumonia and chest infections are frequent sequelae.

Furthermore, a suction catheter is not readily transportable outside a hospital – for example, to a beach, a park or a nursing home. The only truly effective way to clear the lower airways of the lungs is, of course, to cough.

Medical staff members have tried many techniques over the years to stimulate the all-important cough reflex. Methods have included manual pressure

on the front of the neck, blowing dry oxygen down the throat, and tickling the back of the palate with a catheter. None of these methods has proved reliably effective. The catheter-tickling method can sometimes even be dangerous, as the patient can gag and then aspirate the vomitus. In short, no simple method
5 currently exists to stimulate an all-important cough reflex.

The coughing reflex is therefore a natural mechanism wherein air is expelled under force which clears the pulmonary system from the smallest airways toward the trachea. The situation is even more acute with heavily
10 sedated or unconscious patients or animals wherein the smaller airways are blocked and cannot be cleared by the introduction of suction tubes. Respiration can be compromised to the extent where the respiratory centre is completely depressed through hypoxia and the patient or animal eventually dies from asphyxiation, infection or pneumonia.

OBJECT OF THE PRESENT INVENTION

It is therefore an object of the present invention to seek to alleviate or ameliorate some of the limitations and disadvantages of the prior art or to at least provide the public with a useful choice.

STATEMENT OF THE INVENTION

In one aspect, the invention resides in an apparatus for inducing a coughing reflex in a person or an animal including:

25 an ultrasonic wave generation means for producing ultrasonic waves adapted to penetrate soft tissue, wherein in use

on application of the ultrasonic wave generation means to the external
30 neck or throat region, the ultrasonic waves produced stimulate the back of the

neck or the throat thereby facilitating the elicitation of a reflexive coughing response in the person or the animal.

In another aspect, the invention resides in a method of eliciting a reflexive coughing response in a person or an animal including the steps of

5

applying an ultrasonic wave generation means to the external neck or throat region of the patient or animal,

causing ultrasonic waves generated by the ultrasonic wave generation means to penetrate the soft tissue of the neck or throat region thereby

10

eliciting a reflexive coughing response in the person or animal.

Preferably the ultrasonic wave generation means is an ultrasonic transducer array of piezo-electric ceramic material that produces ultrasonic waves when energized by electric current.

15

Preferably the ultrasonic waves provided are of low intensity and within the safe power capabilities of current electrotherapeutic ultrasound apparatus.

Suitably the ultrasonic waves generated penetrate through the soft tissue of the neck or throat through to the pharynx to stimulate a reflexive coughing response.

20

Preferably the reflexive coughing response is due to the stimulation of the cilia that line the pharynx.

Preferably the apparatus is housed in a moulded housing of polyurethane or other similar material.

25

Preferably the housing houses a printed circuit board and other electronic components that modulate the ultrasonic wave.

Preferably the applicator member or head is of a uniquely moulded configuration adapted to fit snugly around the front of a patients or animals neck, just below the chin.

30

Preferably the applicator head houses at least two ultrasound transducers and ensures that the ultrasonic beams are correctly positioned so as to direct the

ultrasonic wave to the correct part of the patients or animals pharynx to ensure that a cough is stimulated.

Preferably the ultrasound parameters are pre-programmed in terms of specific wavelength, intensity, pulsation, wave form, time of application and number of pulses wherein the combination of parameters is the most effective at producing a cough reflex.

Preferably the apparatus will have a power source in the form of a rechargeable battery.

Preferably the power source has battery level and power indicator light.

Preferably the lights are light emitting diodes (LED) wherein a green LED will indicate that the device is in a ready mode.

Preferably the green LED will turn red during the operational or application phase.

Preferably there are skin contact indicators in the form of LED's which will turn red if poor contact is made with the patient's skin.

Preferably the device is of a convenient size and in the order of approximately 30 centimeters long.

Preferably the device has a seamless construction to allow for outdoor and wet area usage and to allow for easy cleaning and sterilization.

Preferably the applicator head is removeably attached wherein a wide variety of applicator head sizes may be interchanged to suit different neck sizes e.g. for paediatric application.

Preferably the applicator heads are detachable by a screw on screw off mechanism in the front of the device.

Preferably the applicator head is adjustable with request to the position of the ultrasound transducer modules.

Preferably the ultrasound modules are mounted on and which protrude from the applicators are spring mounted so that contact is ensured even with the smallest neck wherein the spring mounted modules can retract for necks of larger sizes.

BRIEF DESCRIPTION OF THE DRAWINGS

5 In order that the invention be more readily understood and put into practical effect, reference will now be made to the accompanying illustrations wherein:

10 Figure 1 shows a side and plan view of a preferred embodiment of the invention according to Example 1, and

 Figures 2(a) and 2(b) shows detail of the applicator head of the invention of Figure 1.

DETAILED DESCRIPTION OF THE DRAWINGS

15

 Referring now to Figure 1 there is shown a side view and a plan view of a preferred embodiment of the invention according to example 1. The apparatus 10 for inducing a coughing reflex includes an applicator head 12 wherein they are mounted ultrasonic wave generation means in the form of piezo-electric ceramic components 14, 16 which generate ultrasonic waves when energised by electric current. The body of the apparatus preferably houses a rechargeable battery source. Shown in the side view is a handle 18 for carrying the apparatus which has various indicator lights such as an off/on indicator light 20, and a battery level indicator 22. On the handle there is shown an activator button 30 which switches 25 on the electric current in order to energise the piezo-electric ceramic modules. The applicator is shown having a curved configuration which is adapted to fit around the neck or throat region of a patient or animal. Preferably the applicator can be removed from the body of the apparatus so that various shaped applicators can be interchangeably used. There are also shown some option 30 setting buttons 24, 26, 28 preferably to set the level of ultrasonic generation by the piezo-electric ceramic modules depending on the intensity required.

Figures 2(a) and 2(b) shows detail of the applicator head 12. Figure 2(a) is a plan view showing the curved configuration of the applicator head wherein the piezo-electric ceramic modules 14, 16 are located so that the ultrasound waves generated are directed to a target area at the back of the throat or neck.

5 The concentration of the ultrasonic waves generated stimulates the back of the throat preferably the smooth muscle and cilia of the upper trachea in order to induce a coughing spasm or reflex thereby clearing the chest.

Figure 2(b) shows a side view of the applicator head 12 wherein the piezo-electric ceramic module 14 is mounted in the body of the applicator head which
10 has a portion 13 for inserting onto the body of the apparatus 10 housing the rechargeable battery source.

It will be evident that in order for the applicator heads to be interchangeable they should be removeably attached to the body of the apparatus by means possibly of a detent mechanism or a push button locking
15 mechanism 40.

The inventor's research suggests that the cough reflex starts with infinitesimal hair-like structures, known as cilia, which line the pharynx. When debris or dust is inhaled, the cilia vibrate. This vibration excites nerve endings of the cilia, producing a reflex cough action. The inventor's research team
20 rationalised that if you could artificially create a microscopic vibration of the cilia, then the cilia might be 'tricked' into triggering a cough. How could this micro-vibration be harmlessly achieved? The answer came in the form of ultrasonic waves.

The inventor has examined the effects of various ultrasound parameters
25 such as frequency, intensity, waveform and wave pulse duration, and discovered that certain types of ultrasonic waves would trigger a cough reflex when transmitted through the skin at the front of the neck into the pharynx. The invention is a result of refining a combination of parameters that elicits an instantaneous, reliable cough.

30 The coughing effect can be elicited with a low intensity wave, well within the safe power capabilities of current electrotherapeutic ultrasound apparatus.

Because the sound head is applied to the patient externally, the chances of side effects such as infection is negligible.

The device is preferably small and portable and about the size of a large torch with appropriate electronics housed within the body of the apparatus. The device housing is preferably a light plastic or similar material and the device is activated by a simple push button which triggers a burst of ultrasound waves from the applicator head. The ultrasonic waves are applied through the uniquely shaped applicator head which is placed at the front of the neck of a human patient or an animal. The applicator is preferably u-shaped and houses an ultrasonic transducer array that fits snugly over the front of the throat just below the chin.

Preferably the device may also act to trigger a respiratory cycle in cases in which it has stopped in the same manner as a defibrillator is used to restart the cardiac cycle.

ADVANTAGES

Familiarity:

Medical clientele are comfortable with ultrasound as a tool for treatment and diagnostic purposes, so the technology is not so new to practitioners. Reference will be made to the very safe nature of the modality.

Uniqueness:

No live device currently exists on the market, so the device has the first opportunity to dominate the marketplace, and thereby discourage potential competitors. The company also the first chance to establish relationships and develop brand recognition with customers.

Good use of Technology:

The current solutions to the problem of how to stimulate a cough, such as pushing a catheter into the patient's throat, are crude, unprofessional, and can

even be dangerous. The apparatus represents a safer, more reliable and moreover more technological solution.

Simplicity:

- 5 The technology to produce the device is readily available. Most parts, except for the applicator head and casing, can be purchased off-the-shelf.

Humanitarian benefits:

- 10 The product has humane benefits, and is likely to be well received by the market. This emotive response can also be used in marketing.

Works with trends:

- 15 External factors and trends – for example, our aging population, and the fiscal tightening of health budgets – all help the positioning and promotion of the device.

VARIATIONS

- 20 It will of course be realised that while the foregoing has been given by way of illustrative example of this invention, all such and other modifications and variations thereto as would be apparent to persons skilled in the art are deemed to fall within the broad scope and ambit of this invention as is herein set forth.

- 25 Throughout the description and claims this specification the word "comprise" and variations of that word such as "comprises" and "comprising", are not intended to exclude other additives, components, integers or steps.

DATED THIS THIRTEENTH DAY OF DECEMBER 2002

John Dominic Perrier

By his Patent Attorneys

Pipers Patent and Trade Mark Attorneys

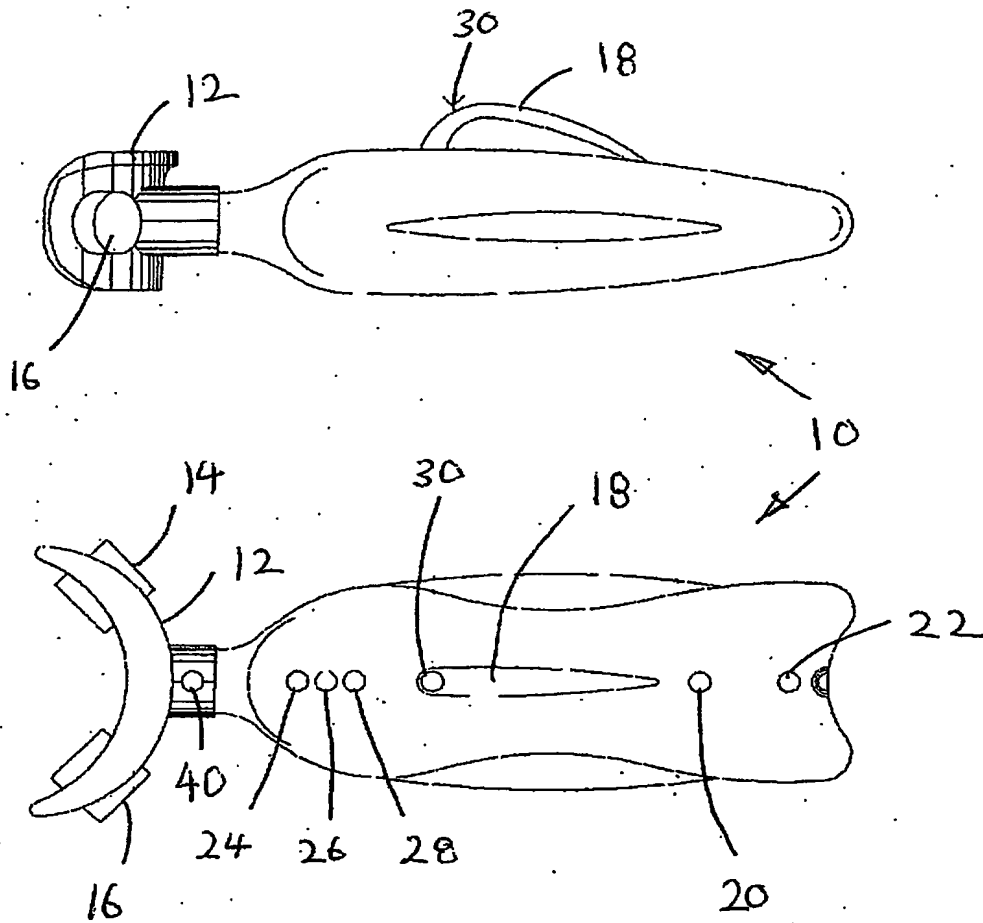


FIG. 1.

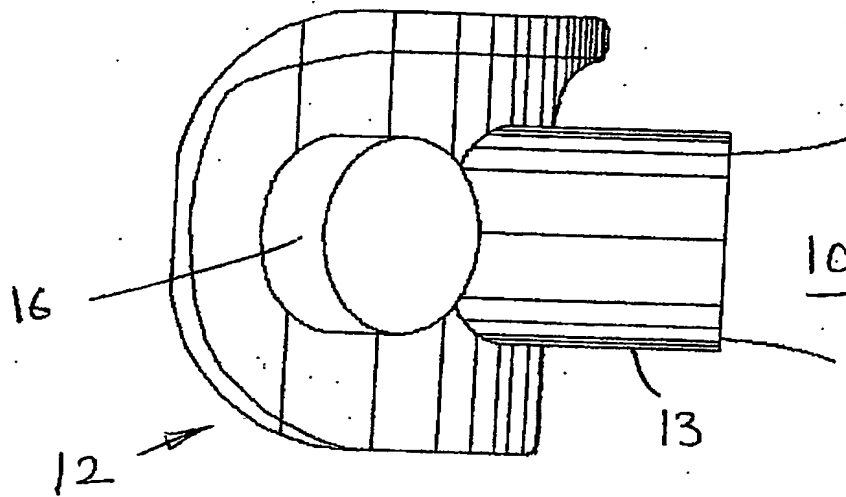


FIG. 2a.

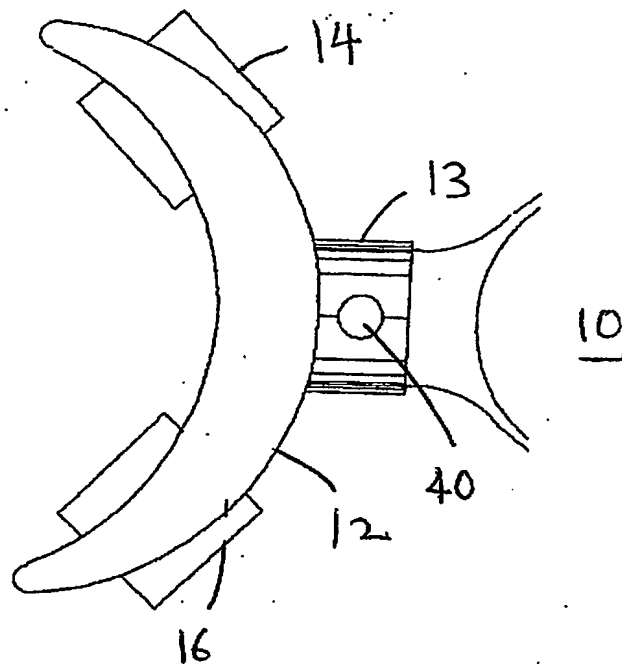


FIG. 2b.